



General

Guideline Title

Diagnosis and management of type 2 diabetes mellitus in adults.

Bibliographic Source(s)

Redmon B, Caccamo D, Flavin P, Michels R, O'Connor P, Roberts J, Smith S, Sperl-Hillen J. Diagnosis and management of type 2 diabetes mellitus in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2014 Jul. 85 p. [197 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Riethof M, Flavin PL, Lindvall B, Michels R, O'Connor P, Redmon P, Retzer K, Roberts J, Smith S, Sperl-Hillen J, Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of type 2 diabetes mellitus in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Apr. 141 p. [198 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [April 8, 2016 – Metformin-containing Drugs](#) : The U.S. Food and Drug Administration (FDA) is requiring labeling changes regarding the recommendations for metformin-containing medicines for diabetes to expand metformin's use in certain patients with reduced kidney function. The current labeling strongly recommends against use of metformin in some patients whose kidneys do not work normally. FDA concluded, from the review of studies published in the medical literature, that metformin can be used safely in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system as a method of assessing the quality of evidence and strength of recommendation.

The recommendations for the management of type 2 diabetes mellitus (T2DM) are presented in the form of 3 algorithms, accompanied by detailed annotations. Algorithms are provided in the [original guideline document](#) for: Diagnosis, Management, and Cardiovascular Risk Management; clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Quality of evidence (Low Quality, Moderate Quality, and High Quality) and strength of recommendation (Weak or Strong) ratings are defined at the end of the "Major Recommendations" field.

Clinical Highlights

- Education and self-management support is necessary for people with prediabetes and T2DM to manage his/her disease.
- Focus on cardiovascular risk reduction (blood pressure control, low-density lipoprotein cholesterol control primarily with statin use, aspirin use and tobacco cessation).
- Glycated hemoglobin (A1c) levels should be individualized to the patient.
- Aggressive blood pressure control is just as important as glycemic control. Systolic blood pressure level should be the major factor for detection, evaluation, and treatment of hypertension. The use of two or more blood pressure lowering agents is often required to meet blood pressure goal.
- Prevent microvascular complications through annual or biannual eye exams, foot risk assessments and foot care counseling, and annual screening for proteinuria.
- Initial therapy with lifestyle treatment and metformin is advised unless contraindicated.

Diagnostic Algorithm Annotations

1. Assessment and Diagnosis of T2DM

1.1 Body Mass Index (BMI) and Associated Risk Factors of T2DM

Recommendation

A clinician may test asymptomatic patients for T2DM when the patient has a BMI ≥ 25 kg/m² and has one or more additional risk factors (see below), regardless of age. [*Quality of Evidence: Low, Strength of Recommendation: Weak*]

- High-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
- Women who have delivered a baby weighing >9 lb or were diagnosed with gestational diabetes mellitus (GDM)
- Women with polycystic ovarian syndrome
- "Prediabetes" as defined by impaired fasting glucose (IFG), impaired glucose tolerance (IGT) or A1c on previous testing
- Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
- History of first-degree relative with T2DM

Benefits

Patients can develop T2DM without symptoms, and early detection of diabetes allows for earlier implementation of lifestyle modifications and glucose control, and has a legacy effect that can reduce or prevent complications including retinopathy, neuropathy, nephropathy, peripheral vascular disease, and microvascular and cardiovascular disease. Targeted testing for patients of any age who are overweight or obese and have additional risk factors has shown to be cost effective.

Harms

It is unclear for patients with prediabetes that there is a full understanding of which patients will progress to T2DM. Some patients may have increased testing and treatment without benefit, and having the diagnosis of diabetes could potentially have negative psychosocial and economic ramifications for individuals.

Benefits-Harms Assessment

Diabetes screening is potentially costly and has not been proven to result in improved patient outcomes. However, the condition is common, serious, and a cause of serious microvascular and macrovascular health complications. Selective testing of high-risk individuals can reduce the costs compared to universal testing. There are no significant harms to the health of individuals who undergo testing.

Relevant Resources: Casagrande, Cowie, & Fradkin, 2013; Colosia, Palencia, & Khan, 2013; Waugh et al., 2013; Ackermann et al., 2011; Li et al., 2008; Gregg et al., 2004.

1.2 Cardiovascular Risk

Recommendation

A clinician may screen asymptomatic patients for T2DM who have increased cardiovascular risk (see below), regardless of age. [*Quality of Evidence: Low, Strength of Recommendation: Weak*]

- Established atherosclerotic cardiovascular disease (ASCVD)
- Hypertension (blood pressure $\geq 140/90$ mmHg or on hypertension therapy)
- High-density lipoprotein (HDL) cholesterol < 35 mg/dL
- Triglyceride level > 250 mg/dL
- Low-density lipoprotein (LDL) cholesterol > 70 and calculated 10-year cardiovascular event risk $> 7.5\%$ or on lipid-lowering therapy

Benefits

Patients can develop T2DM without symptoms, and early detection of diabetes allows for earlier implementation of lifestyle modifications and glucose control, and has a legacy effect that can reduce or prevent complications including retinopathy, neuropathy, nephropathy, peripheral vascular disease, and other microvascular and macrovascular health complications, and reduce the risk of coronary events. Targeted testing for patients with hypertension has shown to be cost effective.

Harms

It is unclear for patients with prediabetes that there is a full understanding of which patients will progress to T2DM. Some patients may have increased testing and treatment without benefit, and having the diagnosis of diabetes could potentially have negative psychosocial and economic ramifications for individuals.

Benefits-Harms Assessment

Appropriate management of cardiovascular disease and diabetes is supportive of improved mortality and reduction in cardiovascular disease (CVD) events with no significant harms to the health of individuals who undergo screening.

Relevant Resources: Casagrande, Cowie, & Fradkin, 2013; Colosia, Palencia, & Khan, 2013; Waugh et al., 2013; Rahman et al., 2012; Ackermann et al., 2011; American Diabetes Association, 2010; Li et al., 2008; U.S. Preventive Services Task Force (USPSTF), 2008.

1.3 Screening

Recommendation

A clinician should not screen for T2DM in asymptomatic patients without additional risk factors. [*Quality of Evidence: Low, Strength of Recommendation: Strong*]

Benefits

Universal screening incurs substantial costs for initial screening procedures, and many individuals would need to undergo additional testing procedures to confirm or refute the initial screening test, leading to both testing costs and economic costs, such as time away from work or other productive activities. Two randomized trials failed to show a benefit of screening for diabetes on overall mortality. One of these trials found little evidence of benefits from screening on clinical measures of diabetic complications, cardiovascular health, medication use or functional status. In this trial, screening for diabetes appeared to shorten the time to diagnosis of diabetes by only about three years.

Harms

Universal screening would be expected to maximize the number of people diagnosed with diabetes early in their disease process. This would allow for early implementation of therapeutic measures to control hyperglycemia, resulting in a hopefully cost-effective intervention to reduce the incidence of later diabetes-related complications. A randomized trial of screening for diabetes found no evidence of adverse effects of screening on physical or emotional health of screened compared to unscreened individuals.

Benefits-Harms Assessment

The absence of clinical benefit as shown in data from randomized trials and increase in costs would argue against a recommendation for

universal screening in unselected populations or populations judged to be at low risk for diabetes.

Relevant Resources: Waugh et al., 2013; Rahman et al., 2012; Simmons et al., 2012; USPSTF, 2008.

1.4 Diagnostic Testing for T2DM and 1.5 Diagnosis of T2DM

Recommendation

A clinician should diagnose a patient with T2DM through the use of an A1c test with a threshold $\geq 6.5\%$, fasting plasma glucose (FPG) ≥ 126 mg/dL or a two-hour plasma glucose ≥ 200 mg/dL on a 75g oral glucose tolerance test (OGTT). Additionally, if a patient has symptoms of hyperglycemia and casual plasma glucose ≥ 200 mg/dL, diabetes may be diagnosed. [*Quality of Evidence: Low, Strength of Recommendation: Strong*]

Benefits

A1c testing does not require fasting like other methods of testing, which may increase the likelihood that a patient will undergo testing for T2DM and have appropriate diagnosis and treatment. A1c testing also measures chronic glucose exposure over a two- to three-month period and is less influenced by internal factors including stress and/or illness than FPG or OGTT. Both OGTT and FPG are not influenced by abnormal red cell turnover conditions, and both allow for clear guidelines of diagnosis, especially for those who have normal fasting blood sugars.

Harms

A1c testing may miss a portion of the population that would be diagnosed with T2DM using FPG or OGTT criteria, including those that have an abnormal hemoglobins or conditions that affect red blood cell turnover. There may also be racial or ethnic differences in the relationship between glycemia and A1c levels, and these could result in false-negatives or false-positives. FPG and OGTT both require fasting, which may reduce screening rates, and decrease appropriate diagnosis and management due to convenience. The two-hour OGTT is time consuming in both patient fasting and administration.

Benefits-Harms Assessment

The general acceptance of all three testing methods and the specific thresholds are well established. Providing a choice of testing methods is likely to increase the likelihood that appropriate patients are tested for diabetes, minimize cost and inconvenience, and allow clinicians to individualize test selection based on individual patient characteristics.

Relevant Resources: Waugh et al., 2013; American Diabetes Association, 2010; Cowie et al., 2010; Kumar et al., 2010; Olson et al., 2010; International Expert Committee, 2009; Droumaguet et al., 2006.

2. Diagnosis of Prediabetes

Prediabetes: Prediabetes is defined as hyperglycemia that is not sufficient to meet the diagnostic criteria for diabetes, but that is associated with an increased risk of progression to T2DM. Diagnosis of prediabetes is made when an individual meets one or more of the following criteria:

- A1c 5.7% to 6.4%
- FPG of 100 mg/dL to 125 mg/dL
- OGTT two-hour plasma glucose: 140 mg/dL to 199 mg/dL

2.1 Treatment to Prevent or Delay Progression to T2DM

Patients who are identified with prediabetes should be referred for education and life-style interventions to a qualified health professional (which may include clinician, dietitian, nursing staff, and pharmacist).

Effective lifestyle changes include setting achievable goals, obtaining weight loss when needed (between 5% and 10% of total body weight is recommended), and increasing physical activity to a minimum of 150 minutes per week.

- Patients with IGT, IFG or an A1c should be referred to an effective ongoing support program targeting weight loss of 7% of body weight and increasing physical activity to at least 150 minutes per week of moderate activity such as walking.
- Metformin therapy for prevention of T2DM may be considered in those patients meeting criteria for prediabetes.
- At least annual monitoring for the development of diabetes in those with prediabetes may be utilized.
- Screening for and treatment of modifiable risk factors for CVD are suggested.

Patients who respond to lifestyle interventions:

- Annual follow-up and reassessment of risks for developing diabetes

Patients who are high risk and not responding to lifestyle interventions:

- Intensify education and counseling on lifestyle interventions. Lifestyle change remains the preferred method to prevent diabetes.

Health care clinicians should follow patients diagnosed with prediabetes on an annual basis to monitor his/her progress and review treatment goals.

Management Algorithm Annotations

3. Inpatient Diabetes Management

Inpatient care may be appropriate in the following situations:

- Elderly patients with infection or illness, weight loss, dehydration, polyuria or polydipsia
- Life-threatening acute metabolic complications of diabetes
- Uncontrolled insulin-requiring diabetes during pregnancy
- Surgery, infection, steroids – if these conditions cause significant hyperglycemia and rapid initiation of rigorous insulin is needed

The following are suggestions for the inpatient setting:

- Insulin therapy with intravenous insulin in critically ill patients
- Oral glycemic agents may need to be held or the dose adjusted if the patient is hospitalized.
- Use of scheduled insulin, with basal coverage (improves glucose control compared to sliding scale coverage alone)
- For insulin-deficient patients, despite reductions or the absence of caloric intake, basal insulin must be provided to prevent diabetic ketoacidosis
- Target preprandial plasma glucose levels to 90 to 140 mg/dL
- Target random plasma glucose to less than 180 mg/dL
- A protocol should be utilized for patients with hypoglycemia <70 mg/dL
- Establishing a multidisciplinary team that sets and implements institutional guidelines, protocols, and standardized order sets for the hospital results in reduced hypoglycemic and hyperglycemic events

Other considerations include:

- For patients who are alert and demonstrate accurate insulin self-administration and glucose monitoring, insulin self-management should be allowed as an adjunct to standard nurse-delivered diabetes management.
- Patients with no prior history of diabetes who are found to have hyperglycemia (random fasting blood glucose greater than 125 mg/dL or random glucose of 200 mg/dL or more) during hospitalization should have follow-up testing for diabetes within one month of hospital discharge.

Types of Insulin

Based on outpatient studies, consider insulin glargine or detemir as the basal insulin (there are limited inpatient studies to date). Consider using rapid-acting insulin analogs (e.g., lispro, aspart, glulisine instead of regular insulin) unless the patient is to have nothing by mouth or is on continuous feedings. Insulin lispro, glulisine and aspart have similar pharmacokinetics; they have an earlier onset and peak of action than regular insulin. Peak action usually occurs at one hour with a duration of three to four hours, while regular insulin has a peak action of two to four hours and a duration of six to eight hours. Lispro, glulisine and aspart may then reduce the occurrence of late postprandial hypoglycemia compared to regular insulin.

Insulin Dosing Schedule

Insulin dosing schedules must be individualized based on a variety of factors, including the severity of diabetes, oral intake, severity of illness and other concurrent diabetic medication. It is not feasible to design a single algorithm for determining an insulin regimen in every patient. The following information provides general guidance in determining initial insulin doses.

Healthy, non-diabetic people are estimated to secrete approximately 0.4 to 1.0 units of insulin/kg body weight per day. Approximately 50% of this insulin is secreted as basal insulin and 50% as postprandial boluses following meals. Typical daily insulin doses for people with diabetes range from 0.5 to 0.7 units/kg per day. In the United Kingdom Prospective Diabetes Study (UKPDS) of people with T2DM, the median daily insulin dose for people in the intensive insulin treatment arm of the study after a diabetes duration of approximately 12 years was 36 units/day. Fifty percent of subjects were receiving between 23 and 53 units of insulin per day. The average weight of subjects was 75 kg, so the "average" daily insulin requirement was about 0.5 units/kg. Therefore, in initiating subcutaneous insulin in a hospitalized patient who is eating meals, a total daily insulin dose of 0.6 units/kg is probably reasonable. Modification can be made based on clinical judgment for factors such as severity of illness, fragility, renal function, body weight, expected nutritional intake and medication effects (e.g.,

glucocorticoid medications).

Based on the normal physiology of insulin release and experience with outpatient regimens for managing diabetes with subcutaneous insulin, it has been recommended that inpatient subcutaneous insulin regimens comprise three components:

- A basal insulin component
- A prandial insulin component (for patients eating meals)
- A correction, sometimes referred to as "supplemental," insulin component used to treat hyperglycemia before or between meals

See the original guideline document for information on each of these components.

Transition from Intravenous to Subcutaneous Insulin

When transitioning from intravenous to subcutaneous insulin, it is generally recommended that an initial subcutaneous basal insulin dose of long- or intermediate-acting insulin be given prior to discontinuation of the intravenous insulin. Based on the absorption profiles of longer-acting insulins, administering the first subcutaneous insulin dose two hours prior to stopping the insulin infusion would appear to allow sufficient overlap to avoid excessive rebound hyperglycemia when the insulin infusion is discontinued.

Determination of the initial basal insulin dose can be made using the guidelines above (e.g., estimating the basal insulin dose as 40% to 50% of the estimated total daily insulin dose). An alternative method that has been suggested is to estimate the initial basal dose based on the intravenous insulin requirements over a six- to eight-hour period leading up to the transition time. Ideally, this six- to eight-hour period would be a time when the patient was not eating and was not receiving intravenous glucose. The initial basal insulin dose could be calculated as 80% of the estimated 24-hour insulin requirement to provide a margin of safety.

Medication Adherence

Non-adherence with medications can limit the success of therapy and help to explain why a patient is not achieving treatment goals. To screen for non-adherence, clinicians can ask patients open-ended, non-threatening questions at each office visit. The assessment should include probes for factors that can contribute to non-adherence (fear of adverse reactions, misunderstanding of chronic disease treatment, depression, cognitive impairment, complex dosing regimens or financial constraints).

- Assess the patient's knowledge of his/her condition and his/her expectations for treatment
- Assess the patient's medication administration process
- Assess the patient's barriers to adherence

Interventions to enhance medication adherence should be directed at risk factors or causes of non-adherence. Interventions may include simplifying the medication regimen, using reminder systems, involving family or caregivers in care, involving multiple disciplines in team care, providing written and verbal medication instructions, setting collaborative goals with patients, and providing education about medications (including potential adverse effects) and about diabetes in general.

Depression Evaluation

Depression impacts the ability of a person with diabetes to achieve blood glucose control, which in turn impacts the rate of development of diabetes complications. Identification and management of depression are important aspects of diabetes care. Self-administered or professionally administered instruments, such as patient Health Questionnaire (PHQ)-9, are useful adjuncts to the clinical interview in the identification of depression. The NGC summary of ICSI guideline [Adult depression in primary care](#) provides more suggestions for the identification and management of depression. Counseling may be effective, especially among those who are having difficulty adjusting to the diagnosis of diabetes or are having difficulty living with diabetes. Pharmacotherapy for depression is also effective.

Obstructive Sleep Apnea

Sleep apnea is a prevalent condition in obese patients with T2DM and is associated with significant comorbidities including hypertension, cardiovascular disease and insulin resistance. Consider referral of symptomatic patients for sleep evaluation. Clinicians should be cognizant of potential obstructive sleep apnea, especially among obese patients.

See the original guideline document for information on referral to an extended care team including referral to a diabetes educator, endocrinologist/nephrologist, endocrinologist/neurologist, endocrinologist/cardiologist/hypertension specialist, foot care specialist, ophthalmology/optometry, and vascular specialist/surgeon.

4. Glycemic Control and A1c Goals

Recommendation

A clinician should personalize goals with patients diagnosed with T2DM to achieve glycemic control with a hemoglobin A1c <7% to <8% depending on individual patient factors. [*Quality of Evidence: High, Strength of Recommendation: Strong*]

Benefits

Achieving near-normal glycemic control lowers risk of diabetes microvascular complications such as retinopathy, nephropathy and amputations. Achieving A1c of 6.9 to 7.9% may also significantly reduce macrovascular complications based on Steno-2 and UKPDS data.

Harms

Near-normal glycemic control (A1c around 6.4% to 6.5%) achieved through intensive pharmacotherapy appears to have less benefit for major CV events and in one large trial significantly increased mortality 20%. In some patients, aggressive pharmacotherapy with insulin, sulfonylureas or certain other agents may lead to weight gain and severe hypoglycemia. The long-term cardiovascular safety of agents other than metformin and human insulins has yet to be established.

Benefits-Harms Assessment

Therefore, to optimize the balance between benefits and harms for a given patient, personalization of A1c goals in the range of <7% to <8% is recommended.

Relevant Resources: Hemningsen et al., 2013; Callaghan et al., 2012; Anderson et al., 2011; Action to Control Cardiovascular Risk in Diabetes Study Group et al., 2008; ACCORD Study Group, "Effects of medical," 2010; Ismail-Beigi et al., 2010; Duckworth et al., 2009; NICE-SUGAR Study Investigators et al., 2009; Ray et al., 2009; Turnbull et al., 2009; ADVANCE Collaborative Group et al., 2008; Gaede et al., 2008; Holman et al., 2008.

Supplemental Information

For patients with T2DM, an A1c goal of less than 8% may be more appropriate than an A1c goal of less than 7%, when including the following factors:

- Known cardiovascular disease or high cardiovascular risk, and may be determined by the Framingham or American College of Cardiology/American Heart Association (ACC/AHA) Cardiovascular Risk Calculator, or alternatively as having two or more cardiovascular risks (BMI >30, hypertension, dyslipidemia, smoking and microalbuminuria)
- Inability to recognize and treat hypoglycemia, including a history of severe hypoglycemia requiring assistance
- Inability to comply with standard goals, such as polypharmacy issues
- Limited life expectancy or estimated survival of less than 10 years
- Cognitive impairment
- Extensive comorbid conditions such as renal failure, liver failure and end-stage disease complications

See the original guideline document for information on multifactorial approach, microvascular/macrovascular complications, cardiovascular risk, glycosylated hemoglobin assays, and self-monitoring blood glucose (SMBG). Also, Table 1 in the original guideline document provides ranges of self-monitored blood glucose values for various A1c goals.

5. Education and Self-Management

5.1 Nutrition Therapy

Recommendation

A qualified health professional (which may include a clinician, dietitian, nursing staff and pharmacist) should provide nutrition therapy to a patient diagnosed with T2DM as part of a global treatment plan. [*Quality of Evidence: Moderate, Strength of Recommendation: Strong*]

Benefits

Nutrition therapy specifically activates patients by more intensively assessing eating and physical activity behaviors and nutrient intake, and provides counseling that results in improved health and may reduce complication of T2DM. Diabetes nutrition therapy can result in cost savings and improved outcomes such as reduction in A1c. Nutrition therapy can be personalized based upon the patient's needs, comorbidities, existing chronic conditions and other key factors.

Harms

Professionals who do not utilize evidence-based standards/protocols can promote expensive short-term strategies that limit food choices – without scientific evidence – that are not ultimately effective in improving long-term health. Patient activation can be difficult and may not be sustainable for the patient long term, and the increased cost for healthy foods may be a burden for some.

Benefits-Harms Assessment

The benefit of having a patient activated and counseled based upon his/her needs and the increase of risk reduction outweighs the difficulty in achieving nutrition modification.

Relevant Resources: Ajala, English, & Pinkney, 2013; Estruch et al., 2013; Andrews et al., 2011; Azadbakht et al., 2011; Elhayany et al., 2010; Brehm et al., 2009; Esposito et al., 2009; Robbins et al., 2008; Brunerova et al., 2007; Nield et al., 2007; Ash et al., 2003

Recommendation

A qualified health care professional (which may include a clinician, nursing staff, pharmacist, and registered dietitian) should counsel a patient diagnosed with T2DM to modify his/her diet to reduce sodium intake to <2,300 mg/day (*Strong*). Clinicians may counsel patients diagnosed with T2DM and hypertension to further reduce their sodium intake (*Weak*). [*Quality of Evidence: High, Strength of Recommendation: Strong/Weak*]

Benefits

Incrementally lower sodium intakes have shown beneficial effects on blood pressure and mitigation of cardiovascular risk factors with such meal plans as the Dietary Approaches to Stop Hypertension (DASH) diet.

Harms

There is difficulty in achieving both low-sodium recommendations and a nutritionally adequate diet, given such concerns as cost, palatability and availability of lower sodium food products.

Benefits-Harms Assessment

The beneficial effects on blood pressure and mitigation of cardiovascular risk factors outweigh the inconvenience and cost of finding a diet with a reduced sodium intake. Sodium intake <1,500 mg/day has shown to be associated with a small increase in mortality, and counseling a patient to reduce sodium intake to <2,300 mg/day should be considered only on an individual basis with consideration.

Relevant Resources: He, Li, & MacGregor, 2013; Suckling, He, & MacGregor, 2010

Recommendation

A qualified health care professional (which may include a clinician, dietitian, nursing staff and pharmacist) may give a patient diagnosed with T2DM a meal plan that incorporates monitoring carbohydrates. [*Quality of Evidence: Moderate, Strength of Recommendation: Weak*]

Benefits

A customized diabetes meal plan that includes the amount of carbohydrate in meals and snacks to improve postprandial glycemia is effective in achieving glycemic control. Carbohydrate intake has a direct effect on postprandial glucose levels and is the macronutrient most of concern in glycemic management. Simplified plate methods that including portion-controlled carbohydrate food sources may be better suited for patients with numeracy and literacy concerns. Carbohydrate intake from vegetables, fruits, whole grains, legumes and dairy products should be advised over intake from other carbohydrate sources, especially those that contain added fats, sugars or sodium.

Harms

Meal plans that do not adjust for total amount of carbohydrates can result in higher than desired target ranges for postprandial blood glucoses and HgbA1c. If the patient is not given a meal plan at the appropriate literacy level, the ability for the patient to effectively monitor carbohydrates may be difficult and produce less than ideal outcomes.

Benefits-Harms Assessment

Monitoring carbohydrate intake, whether by carbohydrate counting or experience-based estimation, remains a key strategy in achieving glycemic control and outweighs the difficulty in achieving nutrition modification.

Relevant Resources: Ajala, English, & Pinkney, 2013; Estruch et al., 2013; Azadbakht et al., 2011; Wiebe et al., 2011; Elhayany et al.,

2010; Brehm et al., 2009; Esposito et al., 2009; Thomas & Elliott, 2009; Brunerova et al., 2007.

See the original guideline document for information on supplemental information, including nutrition assessment, goals and eating patterns, macronutrients, meal planning approaches, carbohydrate intake, sucrose, fiber, glycemic index, non-nutritive sweeteners, protein, fat intake, monounsaturated fatty acids (MUFA), omega-3, sodium, and alcohol.

5.2 Physical Activity

Recommendation

A clinician should advise patients diagnosed with T2DM to complete at least 150 minutes a week of aerobic physical activity and resistance training at least twice per week. [*Quality of Evidence: High, Strength of Recommendation: Strong*]

Benefits

Exercise is a low-cost, non-pharmacological intervention that has been shown to have a beneficial effect on decreasing metabolic risk factors for the development of complications and cardiovascular disease. Lowering glucose may reduce medication needs via muscle mass development, HgbA1c levels, improve insulin sensitivity, bone density and balance; and it is well tolerated, feasible and safe.

Harms

Behavior modification may be difficult and challenging to maintain. Concern is that acute rises in blood pressure associated with higher intensity resistance exercise might be harmful, possibly provoking stroke, myocardial ischemia or retinal hemorrhage. Also muscle soreness, fatigue and injury potential are additional harms that may be associated with physical activity.

Benefits-Harms Assessment

The benefit that exercise has shown to provide in lowering the effects of T2DM and its cost saving outweigh the difficulty in achieving behavior modification and the low risk of cardiovascular events due to acute rises in blood pressure.

Relevant Resources: Gibbs et al., 2014; Look AHEAD Research Group et al., 2013; Church et al., 2010; Li et al., 2010; Diabetes Prevention Program Research Group et al., 2009; Thomas & Elliot, 2009; Orozco et al., 2008; Nield et al., 2007; Cauza et al., 2005; Sigal et al., 2004; Castaneda et al., 2002; Dunstan et al., 2002; Boulé et al., 2001.

Supplemental Information

Strategies for initiation of increased physical activity:

- Start by incorporating 10 minutes of increased activity into each day
- Overcome barriers
- Reinforce the ongoing need and benefits of physical activity at each visit

See the original guideline document for additional supplemental information.

5.3 Weight Management

Recommendation

A qualified health professional (which may include a clinician, dietitian, nursing staff and pharmacist) should counsel an overweight patient diagnosed with T2DM about the need to reduce energy intake while maintaining a healthful eating pattern to promote weight loss. [*Quality of Evidence: Moderate, Strength of Recommendation: Strong*]

Benefits

Various energy-restricted eating patterns have been utilized to reduce excess body weight with no specific optimal macronutrient intake to support weight reduction established. A variety of eating patterns has resulted in reduction of energy with weight loss and subsequent improvement in diabetes control and other cardiovascular risk factors.

Harms

Maintaining a nutritional therapy change may be difficult for a patient long term and may not be sustained. Unqualified health advisors may recommend overly restrictive diet regimens that result in nutritional deficiencies and/or rapid extreme weight loss, which may contribute to medical conditions such as gallstones.

Benefits-Harms Assessment

The benefits of a healthier lifestyle outweigh the harms associated with sustainability and the potential for nutritional deficiencies or rapid extreme weight loss. Weight loss and a healthier lifestyle are difficult to sustain, but even small amounts of weight loss and reduction in energy intake can improve outcomes.

Relevant Resources: Look AHEAD Research Group et al., 2013; Buchwald et al., 2009; Diabetes Prevention Program Research Group et al., 2009; Norris et al., 2005; Ash et al., 2003.

Supplemental Information

The optimal macronutrient distribution of weight loss diets has not been established. Studies designed to reduce excess body weight have used a variety of energy-restricted eating patterns with various macronutrient intake, and some included physical activity and ongoing follow-up support. Clinicians should collaborate with overweight or obese individuals with diabetes to develop healthful eating plans that reduce energy to promote weight loss. An eating plan should include appropriate food choices, and portion size needs to reflect energy requirements to ensure appropriate energy balance. Maintenance of weight loss requires an intensive program with long-term support.

See the NGC summary of the ICSI guideline [Prevention and management of obesity for adults](#) for recommended lifestyle strategies.

5.4 Bariatric Surgery

Recommendation

A clinician may recommend a patient diagnosed with T2DM and a BMI >35 kg/m² consider bariatric surgery if diabetes or comorbidities are difficult to control with lifestyle and pharmacologic therapy. [*Quality of Evidence: Moderate, Strength of Recommendation: Weak*]

Benefits

Large amounts of weight loss – which can be achieved with bariatric surgery, at least in the short term – in resolution of diabetes or improved diabetes control and elimination or reduction in diabetes medications compared to intensive medical management.

Harms

Bariatric surgery carries a risk of perioperative mortality and perioperative, and long-term complications from surgery. Whether bariatric surgery results in long-term reduced mortality or risk of cardiovascular events compared to intensive medical management is unknown.

Benefits-Harms Assessment

The potential for resolution or substantial improvement in diabetes with bariatric surgery could outweigh the potential harms from surgery for appropriate patients who wish to consider this option.

Relevant Resources: Ikramuddin et al., 2013; Cohen et al., 2012; Dorman et al., 2012; Mingrone et al., 2012; Schauer et al., 2012; Maciejewski et al., 2011; Hoerger et al., 2010; Makary et al., 2010; Buchwald et al., 2009

5.5 General Diabetes Self-Management and Education

Recommendation

Diabetes self-management or education by a qualified health care professional (which may include a clinician, dietitian, nursing staff and pharmacist) should be offered to patients diagnosed with T2DM. [*Quality of Evidence: High, Strength of Recommendation: Strong*]

Benefits

Diabetes self-management education and support improves patient understanding of the disease, empowers patients to manage their care, and reduces distress. It is cost effective and has been shown to improve knowledge, self-efficacy and self-care behavior skills, and modestly improves glycemic control.

Harms

Patients may find it difficult to continue education due to the ongoing time commitment and expense.

Benefits-Harms Assessment

Benefit of providing education and support strongly outweighs any potential harms.

Relevant Resources: Guicciardi et al., 2014; Lakerveld et al., 2013; Pal et al., 2013; Thorpe et al., 2013; Steinsbekk et al., 2012; Tshianganga et al., 2012; Tricco et al., 2012; Gillett, 2010; Radhakrishnan, 2012; Deakin et al., 2009; Duke, Colagiuri, & Colagiuri, 2009; Robbins et al., 2008; Gary et al., 2003; Siminerio, 2006; Siminerio et al., 2006; Siminerio, Piatt, & Zgibor, 2005

See the original guideline document for additional information on diabetes self-management and education.

5.6 Foot Care Education

Education should be tailored to patient's current knowledge, individual needs and risk factors. Patients should be aware of their risk factors and appropriate measures to avoid complications. See "Comprehensive foot exam with risk assessment" in the "Ongoing Management" section below.

Education should include:

- Self-inspect feet daily for cuts, bruises, bleeding, redness and nail problems.
- Wash feet daily and dry thoroughly, including between the toes.
- Do not soak feet unless specified by a health care clinician.
- Be careful of hot water.
- Use of lotions, creams or moisturizer is acceptable, but do not use between the toes.
- Do not walk barefoot.
- Check shoes each day for objects that may have fallen inside, excessive wear or areas that may cause irritation.
- Avoid injuries from cutting toenails; avoid self-cutting calluses or corns.
- When to seek care.

5.7 Tobacco Cessation

Tobacco smoking increases risk of macrovascular complications 4% to 400% in adults with T2DM and also increases risk of macrovascular complications. Over time, tobacco and nicotine products have expanded (including e-cigarettes, water pipes and dissolvable products) and care teams should be advised about these developments in order to screen and counsel appropriately. Tobacco cessation is very likely to be the single most beneficial intervention that is available, and it should be emphasized by clinicians as described below.

- Identify and document tobacco use status.
- Treat every tobacco user. If the patient is unwilling, the clinician should implement motivational treatments.
- Individual, group and telephone counseling are effective, and their effectiveness increases with treatment intensity.
- Practical counseling (problem-solving/skills training and social support delivered as part of the treatment) is an especially effective counseling strategy and should be implemented by clinicians.
- Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these may be used with all patients attempting to quit smoking.
- The combination of counseling and medication is more effective than either alone. Therefore, clinicians should encourage all individuals making a quit attempt to use both.
- Telephone quitline counseling is effective. Therefore, clinicians and health care delivery systems should ensure patient access to quitlines and promote their use. Health and Human Services (HHS) National Quitline (1-800-QUITNOW) connects you to counseling and information about quitting smoking in your state.

6. Metformin

Recommendation

A clinician should initiate metformin as first-line pharmacotherapy for patients with T2DM, unless medically contraindicated. [*Quality of Evidence: High, Strength of Recommendation: Strong*]

Benefits

Metformin may reduce A1c by 1 to 1.5%, rarely causes hypoglycemia when used as monotherapy and does not cause weight gain. It is a low-cost, oral medication with a long track record of accumulated patient experience and safety, and it has a beneficial lipid effect. Metformin can also be used in combination with all other glucose-lowering agents. Improved microvascular and macrovascular outcomes have been demonstrated in large clinical trials. In UKPDS, obese patients treated with metformin had reduced complications and overall mortality.

Harms

The most common side effects are diarrhea, gas and nausea. These side effects can be attenuated by initiating metformin at a low dose and increasing gradually over several weeks or months up to the maximum effective dose. The risk of lactic acidosis, a rare but potentially life-threatening condition, may be increased due to metformin but data are controversial. Conditions that predispose patients to hypoxemia, such as symptomatic congestive heart failure (CHF) or chronic obstructive pulmonary disease (COPD) can increase the risk of lactic acidosis. The kidneys clear metformin, and the product label contraindications relate to specific creatinine thresholds. However, other data indicate that metformin seems safe and can be initiated in labeled doses if the glomerular filtration rate (GFR) is above 45 ml/min, with close monitoring of renal function and continued treatment unless the GFR falls to <30 ml/min. Metformin should be stopped before surgery or contrast studies with radiographic dye injection for at least 48 hours and until adequate post-event renal function is documented. Long-term metformin use has been associated with vitamin B12 deficiency.

Benefits-Harms Assessment

The benefits of metformin outweigh the harms for most patients. Monitoring of renal function and conditions that may predispose to lactic acidosis reduce the potential risk. Metformin alone may not be sufficient to achieve recommended blood glucose goals in patients presenting with severe hypoglycemia.

Relevant Resources: Al-Shareef, Sanneh, & Aljoudi, 2012; Lipska, Bailey, & Inzucchi, 2011; Salpeter et al., 2010; Selvin et al., 2008; Saenz et al., 2005; U.K. Prospective Diabetes Study (UKPDS), 1998

Cardiovascular Risk Management Algorithm Annotations

7. Cardiovascular Risk Factors

7.1 Antihypertensive Therapy

Recommendation

A clinician should initiate antihypertensive treatment for patients with T2DM with a blood pressure $\geq 140/90$ mmHg and treat to a goal of $<140/90$. [*Quality of Evidence: High, Strength of Recommendation: Strong*]

Benefits

Uncontrolled hypertension is a major risk factor for ASCVD events. Multiple large studies (UKPDS, Hypertension Optimal Treatment [HOT], Action in Diabetes and Vascular Disease: Preterax and Diamicon modified release [MR] Controlled Evaluation [ADVANCE]) have shown improved cardiovascular outcomes with treatment of blood pressure to this range in patients with diabetes.

Harms

In many patients with diabetes, two or three or more medications are required to achieve this level of blood pressure control. Medications may be costly, and there are risks of adverse reactions, medication interactions and overtreatment causing hypotension.

Benefits-Harms Assessment

Considering the high level of ASCVD risk and the significant benefits for primary and secondary prevention of cardiovascular events in treating hypertension, along with the low cost generic status of the vast majority of antihypertensive medications, it is believed that the benefits of treating hypertension to this goal outweigh the risks. Careful attention should be given to monitoring for side effects, medication interactions and avoiding overtreatment.

Relevant Resources: Arguedas, Leiva, & Wright, 2013; Bangalore et al., 2011; Nilsson, 2011; ACCORD Study Group, "Effects of intensive," 2010; ADVANCE Collaborative Group et al., 2008; Howard et al., 2008; Estacio et al., 2006; Wing et al., 2003; "Major outcomes," 2002; UKPDS Group, 1998; Hansson et al., 1998

See the original guideline document for supplemental information on antihypertensive treatment.

7.2 Statin Therapy (High Risk)

Recommendation

(A) A clinician should recommend high-intensity statin therapy for patients diagnosed with T2DM, between the ages of 40-75 with established ASCVD (*Strong*), and (B) may recommend high-intensity statin therapy for others at a 10-year ASCVD risk $\geq 7.5\%$ (*Weak*).

[*Quality of Evidence: High, Strength of Recommendation: Strong/Weak*]

Benefits

A high-intensity statin reduces the relative risk of ASCVD events more than moderate-intensity statin in patients with and without diabetes, and in primary and secondary prevention in those with diabetes.

Harms

Serious adverse events such as myopathy and rhabdomyolysis are rare, but patient characteristics that may influence statin safety and be cause for not recommending high-intensity statin therapy include multiple concomitant comorbidities, impaired renal or hepatic function, a history of previous statin intolerance or muscle disorders, concomitant use of drugs known to affect statin metabolism, a history of hemorrhagic stroke and age >75.

Benefits-Harms Assessment

The benefits of high-intensity statin therapy for patients with diabetes and high ASCVD risk usually outweigh potential harm, but side effects and individual patient characteristics that predispose patients to statin toxicity can influence the risk/harm balance. Patient preference should be included in decision-making.

Relevant Resources: Taylor et al., 2013; Cholesterol Treatment Trialists (CTT) Collaboration et al., 2010; Cannon et al., 2004; Heart Protection Study Collaboration Group, 2002

7.3 Statin Therapy (Moderate Risk)

Recommendation

A clinician should recommend moderate- or high-intensity statin therapy for all patients diagnosed with T2DM between the ages of 40-75 with a LDL \geq 70 mg/dL. [*Quality of Evidence: High, Strength of Recommendation: Strong/Weak*]

Benefits

The use of at least moderate-intensity statin therapy in persons of this age and an elevated LDL level with a diagnosis of diabetes has been shown to be effective. The only trial of high-intensity therapy in primary prevention was performed in a population without diabetes. High-intensity statin therapy reduces the relative risk of ASCVD events more than moderate-intensity statin therapy in patients with ASCVD. Because individuals with diabetes are at substantially increased lifetime risk for ASCVD events and death, similar to those who have had a previous ASCVD event, persons with diabetes with high estimated 10-year ASCVD risk are likely to benefit similarly from high-intensity therapy.

Harms

Statin therapy appears to cause only a slight increased risk of side effects compared to placebo, and no increased risk of discontinuation of therapy compared to placebo. In clinical practice, the most common side effect observed is muscle symptoms. Some patients who have muscle symptoms can tolerate lower statin doses, changes in statin drugs or alternate-day dosing. Known statin associated serious adverse effects include rare cases of myopathy, hemorrhagic stroke and drug-drug interactions. There are insufficient data to support benefits in individuals with New York Heart Association (NYHA) class II-IV heart failure and individuals undergoing maintenance hemodialysis. Preferences of patients who understand the risks and benefits of statin use should be accounted for, as the potential benefit (especially for primary prevention) may not outweigh the inconvenience and cost of a long-term daily medication with possible side effects for some people.

Benefits-Harms Assessment

Given the high prevalence of macrovascular disease in those with diabetes and the cardiovascular benefit of statins clearly exceeds the risk of adverse events and modest cost for most patients with T2DM ages 40-75. Intensifying statin therapy should be discussed with the patient in a shared decision-making conversation including the risks and benefits. Patients with characteristics that might be predispose them to statin side effects may be candidates for lower intensity statin dosing.

Relevant Resources: Taylor et al., 2013; Macchia et al., 2012; AIM-HIGH Investigators et al., 2011; ACCORD Study Group, "Effects of intensive," 2010; CTT Collaboration, 2010; CTT Collaborators et al., 2008; Cannon et al., 2004; Collins et al., 2003

Supplemental Information

In most patients with diabetes, use of a statin can reduce major vascular events. Beneficial effects of statins on cardiovascular risk reduction may go beyond their quantitative effects on lipid levels.

For those with a diagnosis of diabetes who are younger than 40 or older than 75, statin therapy decisions should be individualized based on considerations of ASCVD risk reduction benefits, potential adverse effects and drug interactions, and patient preferences.

For additional information on statin therapy, refer to the NGC summary of the ICSI guideline [Lipid management in adults](#).

7.4 Aspirin Therapy

Recommendation

A clinician should recommend aspirin therapy for patients diagnosed with T2DM with established ASCVD and consider aspirin therapy for others where the benefits outweighs the risk in primary prevention. [*Quality of Evidence: High, Strength of Recommendation: Strong*]

Benefits

Patients with established ASCVD are at high risk for recurrent events, and aspirin therapy for secondary prevention has been shown to reduce the rate of future events to a clinically meaningful degree. As T2DM is an independent risk factor for ASCVD, patients with T2DM might be expected to benefit from aspirin therapy even before they manifest evidence of ASCVD.

Harms

Aspirin therapy could increase the risk of clinically significant bleeding and is also associated with medication cost.

Benefits-Harms Assessment

The substantial reduction in recurrent ASCVD events with aspirin therapy in secondary prevention will outweigh the risk of bleeding for patients with established ASCVD and no contraindications to aspirin use. In patients with T2DM where aspirin is considered for primary prevention, while the risk of clinically significant bleeding is low, it is still likely increased relative to no therapy. At this time, it is unclear whether adding aspirin therapy to other standard therapy for CV risk factors adds net benefit in patients with T2DM who do not have established ASCVD.

Relevant Resources: Rosiak et al., 2013; Macchia et al., 2012; Soejima et al., 2012; Valentine, Dan de Laar, & van Driel, 2012; Antithrombotic Trialists' [ATT] Collaboration et al., 2009; Belch et al., 2008; Ogawa et al., 2008; Campbell et al., 2007; Pignone & DeWalt, 2006

See the original guideline document for additional information on aspirin therapy.

8. Treatment Goals Not Met

If patients are having difficulty achieving treatment goals, consider the following:

- Modification of treatment goals
- Evaluate for potential contributing issues such as adherence, depression and obstructive sleep apnea.
- A referral to an extended care team clinician can be helpful; this could be to an endocrinologist or other specialist, diabetes educator, dietitian or pharmacist

9. Ongoing Management

Components of ongoing management for successful T2DM care should include the following:

- Regular follow-up with the health care team (via office visit, e-visit, telephone, labs, etc.) should be scheduled yearly. More frequent visits may be necessary if treatment goals are not achieved.
- Patients starting or having a major change in their treatment program (such as initiating insulin therapy) may need to be in contact with their care clinician as often as daily until glucose control is achieved, the risk of hypoglycemia is low, and the patient is competent to conduct the treatment program and should ideally not be delayed greater than one week.
- Perform a targeted history and physical yearly on all patients, with particular attention to the feet, cardiovascular system and blood pressure (see the original guideline document for details).
- Assessment for symptoms of depression
- Weight, BMI
- Blood pressure – all patients with diabetic nephropathy should be on either an angiotensin-converting enzyme (ACE) inhibitor or

angiotensin receptor blocker (ARB)

- Cardiovascular – evaluation of preexisting problems
- Feet (nails, web spaces, calluses, ulcers, structural deformities, protective sensation and shoes)
- At each encounter, ask if the patient has experienced symptoms of hypoglycemia or low blood glucose, review and educate the patient on appropriate recognition, prevention and management. If the patient has a history of severe hypoglycemia (assistance of another person was needed to treat a low glucose) or has developed hypoglycemia unawareness, evaluate the treatment goals for appropriate safety.
- All patients with diabetic nephropathy should be on either an ACE inhibitor or ARB unless contraindicated. Consider early nephrology consultation for patients with macroalbuminuria and/or creatinine (Cr) above 1.5 mg/dL.
- Aggressively control hypertension, dyslipidemia, obesity and protein restriction in all patients with nephropathy.

Specialist Dilated Eye Exam

A dilated eye examination for diabetic eye disease performed by an ophthalmologist or optometrist is recommended annually for patients with T2DM. Less frequent exams (every two to three years) may be considered in the setting of a normal eye exam. The role of fundus photography is still being considered but doesn't replace a comprehensive exam.

Retinopathy

Up to 21% of patients with T2DM are found to have retinopathy at the time of diagnosis of diabetes mellitus. Generally retinopathy progresses from mild background abnormalities to preproliferative retinopathy to proliferative retinopathy.

Poor glucose control is associated with progression of retinopathy. High blood pressure is a risk factor for the development of macular edema and is associated with the development of proliferative retinopathy.

Screening for diabetic retinopathy saves vision at a relatively low cost. In fact, screening costs may be less than the costs of disability payments for those who become blind. Laser photocoagulation surgery is effective in preventing visual loss in diabetic retinopathy.

Renal Assessment and Nephrology

Urinary albumin excretion should be tested annually by a microalbuminuria method. There is racial/ethnic variability with regard to the prevalence of end-stage renal disease with Native Americans, Latinos (especially Mexican Americans), and African Americans having higher rates than non-Hispanic whites with T2DM. If albuminuria is above normal, serum creatinine should be measured.

Screening to Detect Microalbuminuria

Measurement of the albumin-to-creatinine ratio in a random, spot collection. Consider early nephrology consultation for patients with macroalbuminuria and/or Cr >1.5 mg/dL. Aggressive control of hypertension, dyslipidemia, obesity and protein restriction is recommended in all patients with nephropathy.

Several factors can artificially increase the levels of albumin in the urine and should be avoided at the time of the urine collection. These include blood in the urine, prolonged heavy exercise, fever, congestive heart failure, uncontrolled diabetes, severe hypertension, urinary tract infection, and vaginal fluid contamination of specimen.

If two out of three screening microalbuminuria tests are positive, the individual has microalbuminuria and interventions should be considered. A negative finding should be followed annually; a positive finding should be followed periodically, for example annually, to see if the interventions are effective in diminishing the albuminuria.

Nephropathy

In T2DM, albuminuria may be present at the time of diagnosis in about 10% of patients, and another 10% later develop it. Progression to renal failure is less certain in type 2 patients than in type 1 patients, and appears to be modulated by genetic and other factors.

Patients with clinical nephropathy almost always have retinopathy and coronary artery disease.

Numerous interventions are appropriate at different stages of renal function in order to prevent or slow the progression of renal disease and associated cardiovascular disease and include:

- Glucose control – Improved glucose control at any stage of renal function reduces renal disease progression.
- ACE inhibitor or ARB should be used in all nonpregnant patients with micro or macroalbuminuria. For patients with T2DM, ACE inhibitors or ARBs can reduce progression of macrovascular complications. Within one week of initiation, check for elevations in

potassium and creatinine levels.

- Measure serum creatinine at least annually and more often based on stage of chronic kidney disease (CKD).
- Hypertension control – An ACE inhibitor or ARB should be the initial agent of choice. Current Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) and National Kidney Foundation/Disease Outcomes Quality Initiative (NKF/DOQI) recommendations call for treatment of blood pressure to <130/80 in patients with CKD. However, no single, adequately powered intent-to-treat randomized control trial has shown a benefit of this blood pressure goal in CKD. Hence, the recommendation for lower blood pressure goals in all patients with CKD is based on expert opinion and not fully supported by available prospective clinical trials. Determining whether therapy should specifically be titrated to goals lower than 140/90 mmHg for specific subgroups of CKD patients (e.g., those with moderate proteinuria) should be considered on an individual patient basis, based on clinical judgment and patient preference.
- Cardiovascular risk factor intervention – Dyslipidemia is often present with microalbuminuria and should be treated aggressively. Dyslipidemia may be an independent risk factor for progression of renal disease. Smoking is associated with the onset and progression of microalbuminuria.
- Restriction of dietary protein has been shown to slow progression of overt nephropathy (macroalbuminuria), and there may be some benefit in dietary protein reduction in microalbuminuric patients. In these circumstances, protein intake should be reduced to the adult recommended daily allowance of 0.8 to 1 g/kg body weight per day with microalbuminuria present, and 0.8 g/kg body weight per day with macroalbuminuria present.

Treatment for microalbuminuria includes aggressive blood pressure control with ACE or ARB use as first-line therapy, glycemic control, and aggressive cardiovascular risk factor screening and management.

Strongly consider referral to nephrology any patients with a creatinine greater than 1.5 mg or nephrotic range proteinuria (greater than 3 g/24 hr).

Patients with a creatinine clearance of less than 30 mL/min should be referred to nephrology for discussions of future options and to enhance the ability to receive a future transplant. These patients also have significant enough renal impairment that they also benefit from more intensive nutritional interventions and proper management of anemia and bone disease.

See Appendix B, "Treatment of Diabetic Nephropathy," in the original guideline document.

Neuropathy

Peripheral neuropathy is difficult to prevent and treat. Most patients with T2DM and peripheral neuropathy have few symptoms. All patients found to have neuropathy should see a foot care specialist for preventive measures aimed at reducing the incidence of diabetic foot complications. Good glycemic control should be the first control to symptomatic neuropathy.

Comprehensive Foot Exam with Risk Assessment

A foot exam should include assessment for the following risk factor for complications:

- Loss of protective sensation. Protective sensation can be assessed using either a 5.07 Semmes-Weinstein monofilament for light touch or by testing vibration using a 128-Hz tuning fork at the dorsum of the interphalangeal joint of the great toe, or both. Patients with reduced or absent sensation with either of these tests should be educated about their risk and the need for proper foot care to prevent foot complications (see Appendix C, "Using a Semmes-Weinstein Monofilament to Screen the Diabetic Foot for Peripheral Sensory Neuropathy" and Appendix D, "Using a Tuning Fork to Screen the Diabetic Foot for Peripheral Neuropathy" in the original guideline document).
- Peripheral vascular disease (absent pedal pulse, history of claudication, or ischemic skin changes)
- Structural deformities (bunion, hammertoes, Charcot deformity, limited joint mobility, or prior amputation)
- Skin disorders (nail deformity, callus, fissure, tinea, or ulceration)
- Footwear (excessively worn, ill fitting, or inappropriate shoes)
- Medications can improve quality of life in patients with painful neuropathy

Peripheral Vascular Disease

Peripheral arterial disease is commonly associated with diabetes. As many as 36% of patients with diabetes have lower-extremity peripheral arterial disease based on lower-extremity blood pressure readings. However, a typical history of intermittent claudication or an absent peripheral pulse is less commonly noted.

Initial screening for peripheral arterial disease should include asking about claudication and assessment of pedal pulses. Consider obtaining ankle-brachial index if clinically indicated.

Peripheral vascular disease in combination with peripheral neuropathy places patients with diabetes at increased risk for non-traumatic amputations of the lower extremity. Peripheral vascular disease may be slowed by smoking cessation and treatment of hypertension and dyslipidemia.

Aggressive daily foot care, inspection of the feet at every office visit for diabetes mellitus, early treatment of foot infections, treatment of callus, use of moisturizing lotion and proper footwear may forestall problems, including amputation. Vascular surgery may also prevent amputation in some patients with established severe peripheral vascular disease.

Proper high-risk foot management is necessary to prevent ulceration and amputation. Consider referral of patients with claudication and/or absent pedal pulses to vascular surgery.

Cardiovascular and Cerebrovascular Complication Assessment

- History of cardiovascular symptoms such as chest pain, vascular claudication, transient ischemic attack (TIA)
- Cardiac and carotid exams
- Screening for coronary heart disease
- Evaluate cardiovascular status before advising increased intensity of exercise

Cardiovascular and Cerebrovascular Disease

Treatment includes control of cardiovascular risk factors (hypertension, dyslipidemia, and smoking cessation) and aspirin use. Consider referring patients with known coronary artery disease to cardiology and patients with known carotid disease to a specialist.

Heart failure is also common in patients with diabetes. Metformin may be used in stable congestive heart failure if renal function is normal.

Close monitoring of potassium and renal function is necessary especially if patients have concomitant chronic kidney disease as the common use of diuretics, ACE/ARBs and aldosterone antagonists in these patients may cause hyperkalemia and worsening renal function.

Thiazolidinediones should be avoided in patients with congestive heart failure.

For patients with T2DM, thiazide diuretics in the treatment of hypertension can reduce cardiovascular events, particularly heart failure.

Special Considerations

- Hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are <60 years of age. It may be administered to unvaccinated adults with diabetes who are ≥60 years of age.
- Influenza vaccine every year
- Pneumococcal vaccine - repeat the vaccination once after age 65 if the initial vaccination was given prior to 65. Consider repeating the immunization for those at risk of losing immunity after five years including nephrotic syndrome, chronic renal disease, and other immunocompromised states.

Definitions:

Quality of Evidence and Strength of Recommendations

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.

Low Quality Evidence	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms. Very weak recommendation, other alternatives may be equally reasonable.
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Clinical Algorithm(s)

The following detailed and annotated clinical algorithms are provided in the [original guideline document](#) :

- Diagnosis Algorithm
- Management Algorithm
- Cardiovascular Risk Management Algorithm

Additionally, an algorithm titled "Treatment of Diabetic Nephropathy" is provided in Appendix B in the [original guideline document](#) .

Scope

Disease/Condition(s)

- Prediabetes
- Type 2 diabetes mellitus (T2DM)
- Diabetes-associated complications

Other Disease/Condition(s) Addressed

- Atherosclerotic cardiovascular disease (ASCVD)
- Chronic kidney disease
- Cognitive impairment
- Congestive heart failure
- Depression
- Dyslipidemia
- Hypertension
- Liver failure
- Neuropathy
- Obesity
- Obstructive sleep apnea
- Peripheral vascular disease
- Tobacco dependence

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Cardiology

Endocrinology

Family Practice

Internal Medicine

Nephrology

Neurology

Nutrition

Ophthalmology

Podiatry

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Podiatrists

Guideline Objective(s)

- To provide a comprehensive approach to the diagnosis and management of type 2 diabetes mellitus (T2DM) in adults ages 18 and older.
- Diabetes Optimal Care: To increase the percentage of patients, ages 18 to 75 with T2DM who are optimally managed
- Management of T2DM in High-Risk Patients (Trial Measure): To decrease the percentage of adult patients, ages 18 to 75 with T2DM with poorly controlled glucose and cardiovascular risk factors
- Lifestyle Modification and Nutrition Therapy: To increase the percentage of patients ages 18 to 75 years newly diagnosed with T2DM who are advised about lifestyle modification and nutrition therapy

- Medication Management: To increase the percentage of patients with T2DM who are on appropriate medication management

Target Population

Adult patients age 18 and older with prediabetes and type 2 diabetes mellitus (T2DM)

Note: The management of gestational diabetes and T2DM in patients who are pregnant is excluded from the scope of this guideline. Please refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline [Routine prenatal care](#) for information relating to gestational diabetes and T2DM in patients who are pregnant.

Interventions and Practices Considered

Screening/Diagnosis/Evaluation

1. Screen asymptomatic patients for type 2 diabetes mellitus (T2DM) with:
 - Body mass index (BMI) risk factors
 - Cardiovascular risk
2. Glycated hemoglobin (A1c) test
3. Prediabetes diagnosis (hyperglycemia associated with an increased risk of progression to T2DM)

Prevention

1. Lifestyle interventions
2. Education and counseling

Management

1. Inpatient management
2. Insulin therapy
 - Basal (insulin glargine, insulin detemir)
 - Prandial (insulin lispro, insulin aspart, insulin glulisine)
 - Supplemental or correction
 - Individualized dosing schedule
3. Assessment of medication adherence
4. Depression evaluation
5. Obstructive sleep apnea
6. Glycemic control and personalized A1c goals
7. Education and self-management
8. Metformin
9. Cardiovascular management
 - Antihypertensive therapy
 - Statin therapy
 - Aspirin therapy
10. Follow-up
 - Targeted annual history and targeted physical exam
 - Modification of treatment goals
 - Additional assessments (e.g., eye exam, renal assessment, foot exam)

Major Outcomes Considered

- Morbidity and mortality
- Long-term quality of life
- Glycemic control
- Effectiveness of diabetes self-management

- Patient safety

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

This guideline is based on a systematic evidence review evaluating literature published on type 2 diabetes mellitus (T2DM). The literature search was divided into two stages to identify systematic reviews (stage I), and randomized controlled trials, meta-analyses and other literature (stage II). Literature search terms used for this revision are below and include literature from January 1, 2004, through May 31, 2014. Hand searching of identified articles and work group submission was also undertaken.

The databases searched included PubMed and Cochrane. The search was limited to only studies in the English language. The following searches were performed and utilized in this document in regards to T2DM: screening, diagnosis, diagnostic testing, risk factors, bariatric surgery, blood pressure, lipid management, insulin, nutrition therapy, glycemic control, weight loss, metformin, self-management and education.

Number of Source Documents

A total of 143 articles were included for recommendations. See the study selection flow chart document (see the "Availability of Companion Documents" field) for how many articles were used for each recommendation.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence and Strength of Recommendations

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.

Category	Quality Definition	Strong Recommendation	Weak Recommendation
Quality Evidence	Quality Definition is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms. Very weak recommendation, other alternatives may be equally reasonable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

New Guideline Development Process

A work group consisting of 6 to 12 members that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, and an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 work group members may be recruited from medical groups, hospitals or other organizations that are not members of ICSI. Patients on occasion are invited to serve on work groups.

The work group will meet for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 24 months as indicated by changes in clinical practice and literature. For documents that are revised on a 24-month schedule, ICSI checks with the work group on an annual basis to determine if there have been changes in the literature significant enough to cause the document to be revised earlier or later than scheduled. For yearly reviewed documents, ICSI checks with every work group 6 months before the scheduled revision to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Literature Search

ICSI staff, working with the work group to identify any new pertinent clinical trials, systematic reviews, or regulatory statements and other professional guidelines, conduct a literature search.

Revision

The work group will meet for 1 to 2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

A second review by members is indicated if there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations. If a review by members is not needed, the document goes to the appropriate steering committee for approval according to the criteria outlined in the "Description of Method of Guideline Validation" field.

Rating Scheme for the Strength of the Recommendations

See the "Rating Scheme for the Strength of the Evidence" field.

Cost Analysis

- Targeted testing for patients of any age who are overweight or obese and have additional risk factors has shown to be cost effective. Targeted testing for patients with hypertension has shown to be cost effective.
- The benefit that exercise has shown to provide in lowering the effects of type 2 diabetes and its cost saving outweigh the difficulty in achieving behavior modification and the low risk of cardiovascular events due to acute rises in blood pressure.
- Diabetes self-management education and support is cost effective and has been shown to improve knowledge, self-efficacy and self-care behavior skills, and modestly improves glycemic control.
- Tobacco dependence treatments are both clinically effective and cost effective.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Critical Review Process

The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Document Approval

Each document is approved by the Committee for Evidence-Based Practice (CEBP).

The committee will review and approve each guideline/protocol, based on the following criteria:

- The aim(s) of the document is clearly and specifically described.
- The need for and importance of the document is clearly stated.
- The work group included individuals from all relevant professional groups and had the needed expertise.
- Patient views and preferences were sought and included.
- The work group has responded to all feedback and criticisms reasonably.
- Potential conflicts of interest were disclosed and do not detract from the quality of the document.
- Systematic methods were used to search for the evidence to assure completeness and currency.
- Health benefits, side effects, risks and patient preferences have been considered in formulating recommendations.
- The link between the recommendation and supporting evidence is clear.
- Where the evidence has not been well established, recommendations based on community practice or expert opinion are clearly identified.
- Recommendations are specific and unambiguous.

- Different options for clinical management are clearly presented.
- Clinical highlights and recommendations are easily identifiable.
- Implementation recommendations identify key strategies for *health care systems* to support implementation of the document.
- The document is supported with practical and useful tools to ease *clinician* implementation.
- Where local resource availability may vary, alternative recommendations are clear.
- Suggested measures are clear and useful for quality/process improvement efforts.

Once the document has been approved, it is posted on the ICSI Web site and released to members for use.

Evidence Supporting the Recommendations

References Supporting the Recommendations

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is classified for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Patients can develop type 2 diabetes mellitus (T2DM) without symptoms, and early detection of diabetes allows for earlier implementation of lifestyle modifications and glucose control, and has a legacy effect that can reduce or prevent complications including retinopathy, neuropathy, nephropathy, peripheral vascular disease, and other microvascular and macrovascular health complications, and reduce the risk of coronary events.

See the "Benefits" and "Benefits-Harms Assessment" sections in the "Major Recommendations" field for additional benefits of specific interventions.

Potential Harms

- Oral agents do not have U.S. Food and Drug Administration (FDA) approval for use in pregnancy.
- For patients with corticosteroid-induced hyperglycemia, caution is suggested in prescribing correction dose insulin at bedtime due to the increased risk of nocturnal hypoglycemia.
- Hypoglycemia is a risk in individuals who participate in physical activity and are taking insulin and/or insulin secretagogues. Depending on the level of physical activity, the medication dosage or the amount of carbohydrate ingested, hypoglycemia can occur. For patients on these drug classes and pre-exercise glucose monitor results less than 100 mg/dL, additional carbohydrate should be ingested for prevention of hypoglycemia.
- Regular use of ibuprofen may undermine aspirin's anti-platelet effects; patients taking both medications regularly should take immediate-release aspirin at least 30 minutes prior to taking ibuprofen or wait at least eight hours after ingestion of ibuprofen.
- Efforts to achieve glycated hemoglobin (A1c) below 7% may increase risk of mortality, weight gain, hypoglycemia and other adverse effects in many patients with type 2 diabetes mellitus (T2DM).

See the "Harms" and "Benefits-Harms Assessment" sections in the "Major Recommendations" field for additional harms of specific interventions.

Contraindications

Contraindications

- The kidneys clear metformin, and the product label contraindications relate to specific creatinine thresholds.
- Clinicians should use clinical judgment and assess for conditions that might contraindicate certain types of exercises or be predisposed to injury (e.g., uncontrolled hypertension, severe autonomic neuropathy, severe peripheral autonomic neuropathy or history of foot lesions).

Qualifying Statements

Qualifying Statements

- The information contained in this Institute for Clinical Systems Improvement (ICSI) Health Care Guideline is intended primarily for health professionals and other expert audiences.
- This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.
- This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Implementation of the Guideline

Description of Implementation Strategy

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Implementation Recommendations Highlights

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

The implementation of type 2 diabetes mellitus (T2DM) clinical guidelines at medical groups and clinics is a complex and challenging task. However, a number of key processes have been shown to accelerate effective clinical guideline implementation and care improvement. These overlapping care elements can be categorized at the medical group and clinician levels:

- Essential elements at the medical group level:
 - Leadership. Medical group leaders must communicate the need for change in clinical practice patterns and consistently identify improvement priorities.
 - Resources. Resources adequate to the task at hand will be needed to assure the success of a change effort. Resources may include staff time, money and provision of tools (such as electronic medical records) to support care improvement.
 - Select specific improvement goals and measures. For most chronic diseases, including diabetes, the most efficient improvement strategy is to focus on a limited number of specific improvement goals. These may be based on observed gaps in care, potential clinical impact, cost considerations or other criteria. In T2DM, focusing on glycemic control, lipid control and blood pressure control is a strategy that has been shown to be effective in preventing up to 53% of heart attacks and strokes, the leading drivers of excess mortality and costs in adults with diabetes.
 - Accountability. Accountability within the medical group is a management responsibility, but external accountability may also play an important enhancing role to motivate sustained efforts to implement guidelines and improve care. Examples of external accountability include participation in shared learning activities or public reporting of results (such as in pay-for-performance or the Minnesota Community Measures Project).
 - Prepared practice teams. The medical group may need to foster the development of prepared practice teams that are designed to meet the many challenges of delivering high-quality chronic disease care.
- Essential Elements at the Clinic Level:
 - Develop "smart" patient registries. These are registries that are designed to identify, automatically monitor, and prioritize patients with diabetes based on their risk, current level of control, and possibly patient readiness-to-change.
 - Assure "value-added" visits. These are office visits or other patient encounters (by phone, e-mail, etc.) that include intensification of treatment if the patient has not yet reached his/her evidence-based clinical goals. Failure of clinicians and patients to intensify treatment when indicated (referred to as "clinical inertia") is a key obstacle to better diabetes care. Previsit planning and best practice prompts may help to increase the efficiency of patient visits and remind clinicians of needed tests and care.
 - Develop "active outreach." These are strategies to reach patients with chronic disease who have not returned for follow-up or for other selected elements of care. Outreach strategies that enhance the likelihood of a future provider encounter that addresses one of the barriers to patient activation may be more effective. Simple reporting of lab test results or care suggestions through the mail may be ineffective at addressing these barriers.
 - Emphasize "patient activation" strategies. These may include diabetes education and other actions designed to sustain engagement of patients with their diabetes care. Many patients with diabetes either (a) do not really believe they have diabetes, or (b) do not really believe that diabetes is a serious disease, or (c) lack motivation for behavioral change, or (d) do not believe that recommended treatments will make a difference to their own outcomes. For care to be effective, these issues must be addressed for many patients.

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Diagnosis and management of type 2 diabetes mellitus (T2DM) in adults: percentage of patients ages 18 to 75 years old with T2DM who are optimally managed, according to the specified components.

Diagnosis and management of type 2 diabetes mellitus (T2DM) in adults: percentage of patients ages 18 to 75 years old with T2DM with poorly controlled glucose or any of the specified cardiovascular risk factors.

Diagnosis and management of type 2 diabetes mellitus (T2DM) in adults: percentage of newly diagnosed patients who are advised about lifestyle modification and nutrition therapy within one year of diagnosis.

Diagnosis and management of type 2 diabetes mellitus (T2DM) in adults: percentage of patients ages 40 to 75 years old with untreated LDL greater than 70 mg/dL who are prescribed statin therapy.

Diagnosis and management of type 2 diabetes mellitus (T2DM) in adults: percentage of patients with established ASCVD with documented aspirin use.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 Mar (revised 2014 Jul)

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

The Institute for Clinical Systems Improvement (ICSI) is comprised of 50+ medical group and hospital members representing 9,000 physicians in Minnesota and surrounding areas, and is sponsored by five nonprofit health plans. For a list of sponsors and participating organizations, see the [ICSI Web site](#) .

Source(s) of Funding

- The Institute for Clinical Systems Improvement (ICSI) provided the funding for this guideline. The annual dues of the member medical groups and sponsoring health plans fund ICSI's work. Individuals on the work group are not paid by ICSI, but are supported by their medical group for this work.
- ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups, and sponsoring health plans review and provide feedback, but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Guideline Committee

Committee on Evidence-Based Practice

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

The Institute for Clinical Systems Improvement (ICSI) has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report *Clinical Practice Guidelines We Can Trust* (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at the [ICSI Web site](#) .

Disclosure of Potential Conflicts of Interest

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Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: Lipid Management in Adults, Diagnosis and Treatment of Hypertension

Research Grants: Received institutional payment for research grants from NIH (National Institutes of Health), AHRQ (Agency for Healthcare

Research and Quality), NIMH (National Institute of Mental Health), NHLBI (National Heart, Lung and Blood Institute) and to develop standards of diabetes care for American Diabetes Association

Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: None

Research Grants: NIH (National Institutes of Health) related to ongoing diabetes clinical trial, including the Look Ahead study and GRADE study

Financial/Non-Financial Conflicts of Interest: Consults for the University of Minnesota and Optum Insight and is paid directly to the physician's employer

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Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

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National, Regional, Local Committee Affiliations: None

Guideline Related Activities: Has served on guideline group for BMJ Online T2DM guideline

Research Grants: Receives programmatic support paid to her institution for the following: Stimulated Diabetes Training for Resident Physicians (NIDDK funded), Primary investigator; Personalized Physician Learning for HTN (NHLBI), co-investigator; Priorities (NHLBI), co-investigator; Hyperlink (NHLBI), co-investigator; travel and expenses paid for by an educational grant from Sanofi through the International Diabetes Center

Financial/Non-Financial Conflicts of Interest: None

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Riethof M, Flavin PL, Lindvall B, Michels R, O'Connor P, Redmon P, Retzer K, Roberts J, Smith S, Sperl-Hillen J, Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of type 2 diabetes mellitus in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Apr. 141 p. [198 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](#) .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: [www.icsi.org](#) ; e-mail: icsi.info@icsi.org.

Availability of Companion Documents

The following are available:

- Diagnosis and management of type 2 diabetes mellitus in adults. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement; 2014 Jul. 2 p. Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](#) .
- Diagnosis and management of type 2 diabetes mellitus in adults. Study selection flowchart. Bloomington (MN): Institute for Clinical Systems Improvement; 2014 Jul. 18 p. Electronic copies: Available from the [ICSI Web site](#) .

The appendices in the [original guideline document](#) contain an order set, screening tests, and a sample hypoglycemia protocol.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: [www.icsi.org](#) ; e-mail: icsi.info@icsi.org.

Patient Resources

None available

NGC Status

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